

## **REMARKS**

### **1. The Amendments and the Support Therefor**

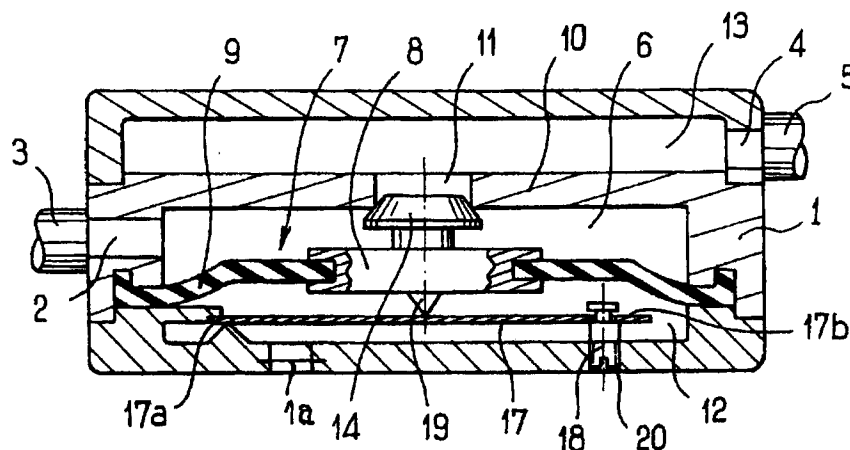
Six claims (7, 26, 40, 50, 51, 59) have been canceled, six new claims (72-77) have been added, and claims 1, 8, 14, 22, 23, 27, 38, 41, 42, 48, 52, 53, 58, and 64 have been amended to leave claims 1-6, 8-25, 27-39, 41-49, 52-58, and 60-71 in the application. No new matter has been added by the amendments or new claims, wherein:

- **Independent claim 1** has been amended to incorporate its dependent claim 7.
- **Claim 8** is amended to conform to amended claim 1.
- **Claim 14** is amended to correct a spelling error.
- **Independent claim 22** has been amended to incorporate its dependent claim 26.
- **Claim 23** is amended to provide clear antecedent basis for the recited diaphragm.
- **Claim 27** is amended to provide clear antecedent basis for the recited diaphragm.
- **Independent claim 38** has been amended to incorporate its dependent claim 50.
- **Claim 41** is amended to provide clear antecedent basis for the recited piston.
- **Claim 42** is amended to conform to amended claim 38.
- **Claim 48** is amended to conform to amended claim 38.
- **Claim 52** is amended to clarify antecedent basis for the recited piston.
- **Claim 53** is amended to clarify antecedent basis for the recited piston.
- **Independent claim 58** has been amended to incorporate its dependent claim 59.
- **Claim 64** is amended to clarify the location of the fluid flow being referred to.
- New **claims 72-77** particularly find support in FIG. 3 and page 11 onward (starting at the final paragraph on page 11).

Further comments regarding the new claims are set out below at Section 5.

**2. Sections 1-8 of the Office Action: Rejection of Claims 1, 2, 5, 6, 11-15, 17-25, 27-30, 33-45, 50, 51, 55-60, 62, 64, 68-71 under 35 USC §102 in view of U.S. Patent 5,643,195 to Drevet**

Before discussing the rejections, it is initially useful to review U.S. Patent 5,643,195 to *Drevet*. *Drevet*'s shunt, in FIG. 1 (reproduced below), includes an inlet port 3 opening onto a fluid passageway 11 extending between an upstream side 6 and a downstream side 13, with the downstream side 13 opening onto an outlet 5 (column 4 lines 46-63). A valve 14 having a piston head is situated between the upstream side 6 and the downstream side 13 (column 4 line 64-column 5 line 1). The piston head is biased to close the fluid passageway 11 by a deformable diaphragm 7 on which the piston 14 rides (column 4 lines 50-52 and 63-65), with one side 12 of the diaphragm 7 being a closed chamber at ambient pressure (column 4 lines 54-56). The piston head is also biased by a leaf spring 17 bearing against a tail end 19 of the piston, wherein the location of the leaf spring 17 (and thus its pressure on the piston) is adjustable via a screw 18 (column 5 lines 10-17). As fluid flows into the upstream side 6 via inlet port 3, if the pressure sufficiently rises in the upstream side 6 to urge the diaphragm 7 and piston 14 downwardly against the spring 17, the piston 14 will open the fluid passageway 11 and allow flow to the downstream side 13 and outlet 5 (column 5 line 24 onward).



**FIG. 1**

***Independent***

**claim 1** has been amended to incorporate its dependent claim 7, with claim 1 thereby reciting a cutout in the piston alignable with a drain port between the upstream and downstream sides to open the valve. Since dependent claim 7 was found novel in view of *Drevet*, the §102 rejections of claim 1 and its dependent claims 2, 5, 6, 11-15, and 17-21 are obviated. (The §103 rejection of claim 7, set forth in Section 11 of the Office Action, will be discussed in Section 4 of this Response below.)

Regarding **dependent claim 5**, rejected under 35 USC §102 at Section 4 of the Office Action, this claim is submitted to be allowable for at least the same reasons as claim 38 (discussed below).

Regarding **dependent claim 17**, rejected under 35 USC §102 at Section 6 of the Office Action, this claim is submitted to be allowable for at least the same reasons as claim 38 (discussed below).

**Independent claim 22** has been amended to incorporate its dependent claim 26, with claim 22 thereby reciting that the valve is defined as a cutout within the movable valve actuating member, with the valve opening when the cutout moves into alignment with the fluid passage. Since dependent claim 26 was found novel in view of *Drevet*, the §102 rejections of claim 22 and its dependent claims 23-25, 27-30, and 33-37 are obviated. (The §103 rejection of claim 26, set forth in Section 11 of the Office Action, will be discussed in Section 4 of this Response below.)

Regarding **dependent claim 24**, rejected under 35 USC §102 at Section 6 of the Office Action, this claim is submitted to be allowable for at least the same reasons as claim 58 (discussed below).

Regarding **dependent claim 33**, rejected under 35 USC §102 at Section 4 of the Office Action, this claim is submitted to be allowable for at least the same reasons as claim 38 (discussed below).

**Independent claim 38** has been amended to incorporate its dependent claim 50, with claim 38 thereby reciting that flow through the valve is oriented at least substantially perpendicular to the direction in which the valve opens/closes. Section 4 of the Office Action rejected dependent claim 50 under 35 USC §102, alleging that “the piston [*of Drevet*] is displaceable along a piston travel axis, and fluid flowing through the valve between the upstream and downstream sides (6 and 13) flows substantially perpendicular to said axis.” However, this is incorrect: in *Drevet*, fluid flowing

through the valve, in the fluid passageway 11 between the upstream side 6 and downstream side 13, clearly flows in a direction oriented at least substantially *parallel* to the piston travel axis along which the piston 14 travels (both travel vertically in the foregoing FIG. 1). Since independent claim 38 is novel in view of *Drevet*, the §102 rejections of claim 38 and its dependent claims 39-45, 50, 51, and 55-57 are obviated. Further, we submit that claim 38 is also unobvious: note that if one looks to *Drevet* and seeks to modify it so that the valve flow is oriented perpendicularly from its present direction (and thus perpendicularly from the direction of valve travel), there is no evident way to modify *Drevet* in this manner.

**Independent claim 58** has been amended to incorporate its dependent claim 59, with claim 58 thereby reciting that the location of the piston is independent of the pressure in the downstream side of the fluid passage. Section 6 of the Office Action rejected dependent claim 59 under 35 USC §102, alleging that “the piston, diaphragm 9, and spring 17 are disposed adjacent the upstream chamber. Therefore, the position of the piston is independent of and isolated from the pressure in the downstream side of the fluid passage.”. However, this is plainly incorrect; note that a major portion of the piston head is exposed to the pressure in the downstream side 13, and will thereby be affected by this pressure. This is evident from column 5 line 24 onward, discussing the behavior of the shunt at various upstream and downstream pressures, in particular, discussing downstream side 13 pressures ranging between -300mm to about 0mm. Claim 58, as amended, is therefore not anticipated by *Drevet*. Since independent claim 58 is novel in view of *Drevet*, the §102 rejections of claim 58 and its dependent claims 59-60, 62, 64, and 68-71 are obviated. Further, we submit that claim 58 is also unobvious: note that if one looks to *Drevet* and seeks to modify it so that the valve behavior is independent of the downstream pressure, there is no evident way to modify it in this manner.

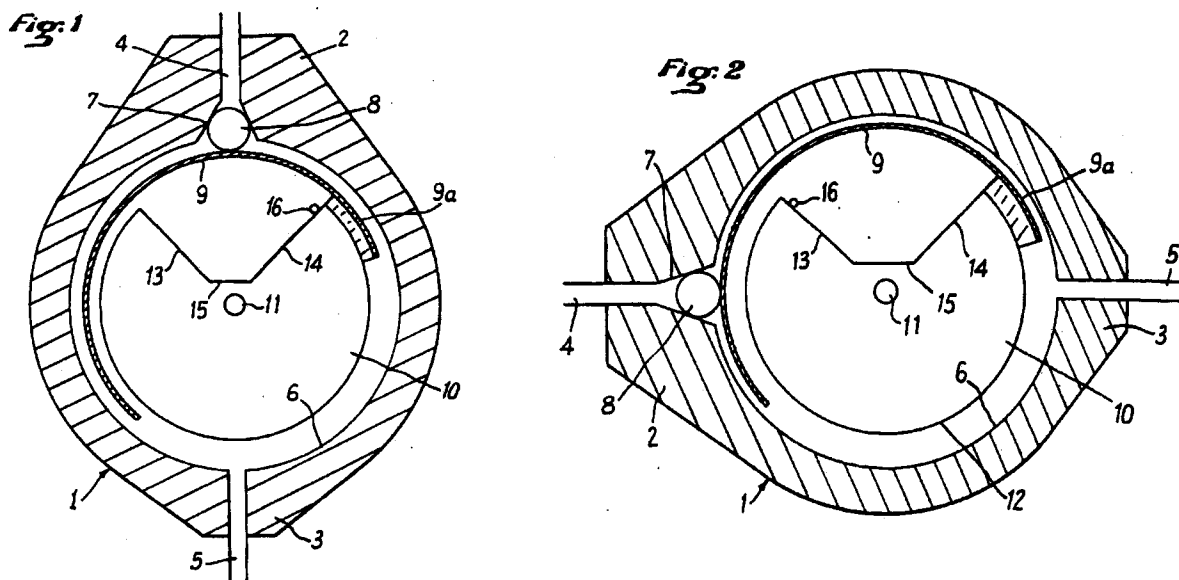
Regarding **dependent claim 64**, rejected under 35 USC §102 at Section 4 of the Office Action, this claim is submitted to be allowable for at least the same reasons as claim 38 (discussed above).

**3. Sections 9-10 of the Office Action: Rejection of Claims 3, 4, 16, 46-49, 61, and 63 under 35 USC §103(a) in view of U.S. Patent 5,643,195 to *Drevet* and U.S. Patent 5,192,265 to *Drake et al.***

These claims are submitted to be allowable for at least the same reasons as their parent claims, whose bases for allowability are discussed in the foregoing and following Sections of this Response.

**4. Section 11 of the Office Action: Rejection of Claims 7-10, 26, 31, 32, 52-54 and 65-67 under 35 USC §103(a) in view of U.S. Patent 5,643,195 to Drevet, U.S. Patent 5,192,265 to Drake et al., and U.S. Patent 4,673,384 to Marion**

U.S. Patent 4,673,384 to *Marion* describes a valve, shown in FIG. 1 as it appears in a standing patient and shown in FIG. 2 as it appears in a lying patient (column 3 lines 14-17):



The valve has an inlet port 4 and an outlet port 5, with a ball valve 8 being situated adjacent the inlet port 4 (column 3 lines 25-34). The ball valve 8 is urged into its seat by an arcuate spring 9 (column 3 lines 35-39), with the spring 9 being affixed to a central rotor 10 at a fixed end 9a (column 3 lines 47-49). A stop 16 defines the extent of rotation of the rotor 10 (column 3 lines 50-54). When the patient stands (FIG. 1), the rotor 10 rotates under gravity (i.e., the heavier half of rotor 10 rotates to the bottom of the valve) so that the spring 9 is urged

against the ball valve 8 closer to its fixed end 9a, thus urging the ball 8 in its seat with greater force. When the patient lays down (FIG. 2), the rotor 10 rotates under gravity so that the free end of the spring 9 is urged against the ball valve 8, thus exerting less force against the ball 8 owing to the greater flexible length of the spring 9, and thus allowing the ball valve to open under lesser fluid pressure. See column 2 lines 60-65, column 3 lines 54-59.

The Office Action states that :

Marion discloses a CSF shunt comprising a flow control valve therein. The valve is formed as a cutout (13, 14, 15) (i.e. a "mask") from a piston element 12, wherein the valve is opened and closed by aligning and unaligning the cutout with the drain port, thereby establishing fluid communication. Furthermore, the valve may be calibrated for any desired closing pressure for implantation (see Abstract). Valves that have cutouts through which fluid is permitted to flow are extremely common in the art of bodily fluid flow control. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the CSF shunt of Drevet with the cut-out-type flow control valve of Marion in order to provide a well-known, alternate means for controlling flow through the valve and regulating pressure across the shunt.

This reasoning is flawed in several respects.

First, the *Marion* valve is *not* opened and closed by aligning and unaligning the "cutout" with the drain port. The "cutout" merely removes weight from a sector of the rotor 10 so that it may rotate under gravity, and it also provides surfaces for engagement by the stop 16; it does not serve as a fluid passage. Rotation of the rotor (and relocation of the "cutout") only changes the amount of spring force applied to the ball valve, which is opened by the inlet fluid pressure. The "cutout" therefore does not open the valve; it merely changes the degree of fluid pressure needed to open the valve.

Second, while the rejection asserts that "[v]alves that have cutouts through which fluid is permitted to flow are extremely common in the art of bodily fluid flow control", this statement is unproven (and is questioned). *Marion* does not have fluid flow through its "cutout" 13, 14, 15; rather, fluid flows from the inlet port 4 to the outlet port 5 about the circumference of the spring 9 and rotor 10.

Third, while the rejection asserts that "it would have been obvious to one of ordinary skill in the art at the time of invention to modify the CSF shunt of Drevet with the cut-out-type flow control valve of Marion", this does not in fact seem to be the case: *how is one to modify Drevet to*

*utilize Marion's valve instead?* The two valves are so profoundly different that one could only "modify" *Drevet* to accommodate *Marion* if one basically replaced *Drevet* with *Marion*. If the Office disagrees, kindly explain how the asserted "modification" is to be executed. The refusal appears to be conclusory, without any reasoning to support the validity of the asserted "modification." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007) ("To facilitate review, this [obviousness] analysis should be made explicit . . . rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). See also MPEP 2141 (quoting *KSR* for the foregoing principle). If the rejection is maintained, please explain: how does one accomplish the asserted modification (i.e., what form would the modified device take), and how does it meet all limitations of the rejected claims?

In addition, Section 11 of the Office Action purports to reject claims 7-10, 26, 31, 32, 52-54 and 65-67. However, the matter recited in claims 8-10, 32, and 53-54 (a deformable mask bearing a cutout, etc.) is not addressed in the rejection, which is contrary to 37 CFR §1.104(c)(2) ("When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified."). No proper *prima facie* case of obviousness has been established for these claims.

**Independent claim 1** incorporates claim 7 (now canceled), which was rejected in view of *Drevet*, *Drake et al.*, and *Marion*. Claim 1 is submitted to be allowable at least because the incorporated matter from claim 7 is novel, and is also unobvious for the reasons noted above (*inter alia*, that *Marion* does not render obvious the recited cutout arrangement).

**Claims 8-10**, dependent from claim 1, are submitted to be allowable because as noted above, no *prima facie* case of obviousness has been established for the recited mask and other features of these claims.

**Independent claim 22** incorporates claim 26 (now canceled), which was rejected in view of *Drevet*, *Drake et al.*, and *Marion*. Claim 22 is submitted to be allowable at least because the incorporated matter from claim 26 is novel, and is also unobvious for the reasons noted above (*inter*

*alia*, that *Marion* does not render obvious the recited cutout arrangement).

**Claim 31**, dependent from claim 22, is submitted to be allowable for at least the same reasons as independent claims 1 and 22 above (*inter alia*, that *Marion* does not render obvious the recited cutout arrangement).

**Claim 32**, dependent from claim 22, is submitted to be allowable because as noted above, no prima facie case of obviousness has been established for the recited mask and other features of this claim.

**Claim 52**, dependent from claim 38, is submitted to be allowable for at least the same reasons as independent claims 1 and 22 above (*inter alia*, that *Marion* does not render obvious the recited cutout arrangement).

**Claims 53-54**, dependent from claim 38, are submitted to be allowable because as noted above, no prima facie case of obviousness has been established for the recited mask and other features of these claims.

## **5. New Claims 72-77**

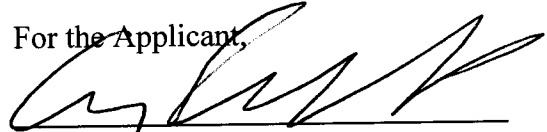
These claims are submitted to be allowable because no art of record discloses or suggests a rotating piston, and/or a piston which rides in a curved path along a guide wall wherein the drain port is defined, and such arrangements are not believed to be in any way evident or foreseeable in view of the state of the art and the level of ordinary skill therein.



**6. In Closing**

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

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